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TO : Commissioner for Patents
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FROM : Oleg F. Kaplun, Esq. of Fay Kaplun & Marcin, LLP

DATE : September 7, 2007

SUBJECT : Endoscopy
U.S. Patent Appln. Serial No. 10/753,848
for *Endoluminal Access Devices and Related Methods of Use*
Inventor(s): Trabada et al.
Our Ref.: 10121/01301

NUMBER OF PAGES INCLUDING COVER : 10

MESSAGE:

Please see attached.

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Attorney Docket No. 10121/01301 (99-0090)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Trabada et al.
Serial No. : 10/753,848
Filed : January 8, 2004
For : Endoluminal Access Devices and Related Methods of Use
Group Art Unit : 3731
Confirmation No. : 6030
Examiner : Glenn K. Dawson

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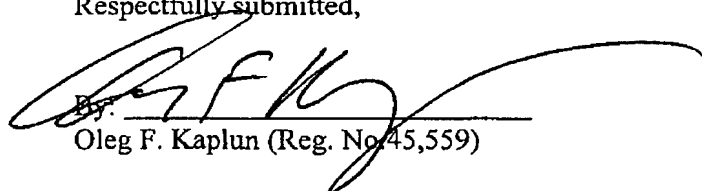
By:  Date: September 7, 2007
Oleg F. Kaplun (Reg. No. 45,559)

TRANSMITTAL

In response to the Final Office Action mailed May 7, 2007 and the Advisory Action mailed July 18, 2007, transmitted herewith please find a Notice of Appeal and a Pre-Appeal Brief Request for Review for filing in the above-identified application. Applicants hereby request a one (1) month extension. Please charge the Credit Card of **Fay Kaplun & Marcin, LLP** in the amount of \$620.00 for the Notice of Appeal filing fee (PTO-Form 2038 is enclosed herewith). The Commissioner is hereby authorized to charge any additional fees which may be deemed necessary to the **Deposit Account of Fay Kaplun & Marcin, LLP No. 50-1492**. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: September 7, 2007


By: _____
Oleg F. Kaplun (Reg. No. 45,559)

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Dated: September 7, 2007

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicants hereby request review of the final rejection in the above-identified application. No amendments are being filed with this Request. This Request is being filed with a Notice of Appeal. The review is requested for the reason(s) stated in the attached Pre-Appeal Brief.

The undersigned is an attorney of record and empowered to sign this Request.

Respectfully submitted,

Dated: September 7, 2007

By: 

Oleg F. Kaplun, Reg. No. 45,559

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PRE-APPEAL BRIEF

In support of the Pre-Appeal Brief Request for Review filed herewith, Applicants present a pre-appeal brief in the above-captioned application.

This is a pre-appeal brief regarding the Examiner's final rejection of claims 1, 2, 4, 5, 7 - 13 and 22 - 25 in the final Office Action dated May 7, 2007 and the Advisory Action of July 18, 2007.

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ARGUMENTI. The Rejection of Claims 1, 2, 4, 5 and 7 - 13 as Obvious Over Richter and Cohen Should be Reversed

In the Final Office Action, the Examiner rejected claims 1, 2, 4, 5 and 7 - 13 under § 103(a) as obvious over Richter (EP Pat. Publ. No. 0 976 417) in view of Cohen (U.S. Patent No. 5,167,239). 05/07/07 Office Action, p. 3. In this Final Office Action, the Examiner stated that Richter shows a guide track and a modular device having an internal motor with an internal gripping surface for gripping the exterior of a catheter and moving an outer catheter relative to an inner catheter but that Richter fails to show an anchoring module selectively coupleable to the guide track. The Examiner then states that "it would have been obvious to have provided a motor on Cohen's guidewire proximally, of the balloon 14, as this would provide means to distally power advancement of the guidewire relative to a catheter." *Id.* In addition, the Examiner stated in the Advisory Action that the 116 Response failed to place the application in condition for allowance because "the combination selectively couples the anchoring module (guide wire with balloon) to the guide track (inner catheter), not to the guidewire."

Initially, it is respectfully submitted that the Examiner himself is unclear as to the grounds of the rejection. That is, the rejection seems to propose that Richter shows all of the claimed elements except for the selectively coupleable anchoring module and that Cohen will somehow cure this defect. However, the above quoted language seems to indicate on the one hand that he proposes adding a motor to the guide wire of Cohen and, on the other hand, that he has proposed combining the guidewire and balloon of Cohen with the device of Richter in a manner which is not fully explained. This is the first time the Examiner has made such a suggestion.

In any case, it is respectfully submitted that the guidewire and balloon of Cohen are suitable for anchoring only the guidewire itself and that, as pointed out in the prior responses to Office Actions in this matter, the balloon of Cohen is permanently mounted to the guidewire. Thus, it is unclear how the Examiner proposes to show "an anchoring module *selectively coupleable to the guide track* for anchoring the guide track at the desired location," as recited in claim 1.

As made clear in the specification of the present application, an anchoring module which is "selectively coupleable" to a guide track may be mounted thereon and removed therefrom as desired. As stated in paragraph 31 of the application, after a guide track 120b has been selected and inserted by the operator into a body lumen 103, an anchor module 150 may be placed on the guide track 120b and advanced to the distal end of the guide track 120b, at which point, an extendible member 152 is expanded to anchor the guide track 120b at the desired position within

the body lumen 103. Then, after the modular device has been removed from the body lumen 103, the extendible member 152 is deflated, and the anchor module 150 is driven along guide track 120b proximally to the external opening of the body lumen 103. *Once the extendible member 152 has been removed from the body lumen 103*, the guide track 120b is withdrawn therefrom. Such "selective coupling" thus necessarily excludes a permanent, irreversible coupling, which is precisely the way anchoring balloon 14 of Cohen is joined to guide wire 12. Specifically, the cross sectional diagram of Figure 3 shows that the material of balloon 14 is affixed in such a way that it is rendered permanently immobile relative to the guidewire 12. Such a permanent joining is necessary so that the interior aperture of the balloon remains aligned with aperture 28 in the guidewire 12, permitting an inflating fluid to be delivered into the balloon cavity. Thus, the combination of Richter and Cohen does not teach the invention of claim 1.

As for claims 2, 4, 5, and 7-13, these claims are patentable for at least the same reasons given above.

Notwithstanding the above argument, Applicants further submit that the Examiner does not provide any evidence to support the rejection of claim 9. Claim 9 further recites that the anchoring module is movable along the guide track. As explained above, the anchoring balloon 14 of Cohen is fixed permanently at one location along guide wire 12. Balloon 14 is thus incapable of moving along guide wire 12. Accordingly, claim 9 is patentable for this additional reason as well.

II. The Rejection of Claims 22 - 25 as Obvious Over Richter and Cohen in Further View of McAllister Should be Reversed

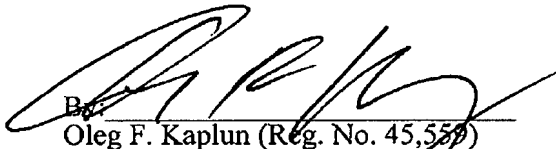
Claims 22 - 25 stand rejected under 35 U.S.C. §103(a) as obvious over Richter in view of Cohen and U.S. Patent Application No. 2002/0065523 to McAlister et al. ("McAlister") (12/27/06 *Office Action*, pg. 6). The Examiner stated that Richter as modified by Cohen shows the invention as claimed with the exception of resection being performed. As indicated above, the Examiner has never made clear what he means by Richter as modified by Cohen. In any case, it is submitted that the device of Richter which is intended to move along a catheter to aid in placement of a stent or other small device within a blood vessel is unsuitable for pushing along a device such as the stapling apparatus of McAllister which is a large device which is manually pushed through a large lumen such as the colon over an endoscope. Furthermore, it is submitted that the endoscope of McAllister obviates the motivation cited by the Examiner -- i.e., the potential buckling of a catheter along which the Richter device would be slid. Thus it is respectfully submitted that one skilled in the art would not be motivated to make the combination suggested by the Examiner and, if such a combination were attempted, it would not result in the

claimed invention as the Cohen and Richter devices are directed to applications entirely distinct from that of McAllister.

For the reasons set forth above, the Applicants respectfully request that the final rejections of claims 1, 2, 4, 5, 7 - 13 and 22 - 25 be reversed and that these claims be allowed.

Respectfully submitted,

Dated: September 7, 2007



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